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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,504	10/26/2001	Yi-Ren Woo	1416.03US01	4675
22865	7590	11/12/2004	EXAMINER	
ALTERA LAW GROUP, LLC 6500 CITY WEST PARKWAY SUITE 100 MINNEAPOLIS, MN 55344-7704			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,504

Applicant(s)

WOO ET AL.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 40-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 40-55 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/12/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 02/12/2004 was filed after the mailing date of the applicant on 10/26/2001. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's arguments with respect to claims 1-2, and 4-21 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 08/13/2004 have been fully considered but they are not persuasive. With regard to the arguments of pages 12-14, it is inherent that the stent of Solovay is rigid enough to hold open a vessel. Solovay discloses that the frame structure can be made unitary with the cover (col 3 lines 41-50) thereby the composite cover is rigid. Rigid is also a relative term subject to interpretation. In the broadest reasonable interpretation of the term "rigid", any material that is in solid form can be considered rigid. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., pores only present substantially near the surface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Solovay can be characterized as having a porous network with pores extending substantially through a rigid

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material based on the broadest reasonable interpretation of the claim and in view of the disclosure in column 4.

Allowable Subject Matter

Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The indicated allowability of claims 3, 46-47 and 55 is withdrawn in view of the newly discovered reference(s) to Alt (US 6099561), Dayton (US 5578075) and Steinke et al (US 6033436). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 15-19, 40-45, 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (US 6099561). Alt discloses an implantable prosthesis (fig. 1A, embodiment '053) comprising a rigid material (metal) with pores (col 5 line 19), wherein a filler comprising a bioactive agent (drugs, col 5, line 23) thereof, is located within the pores, wherein said rigid porous material with the filler presents a smoother surface for fluid flow than pores without filler (this is inherent since a filled pore presents less surface roughness).

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With regard to claims 3, 43 and 52, as presented in claim 1 the filler presents a smooth surfaces to flow as compared to unfilled.

With regard to claim 4, filled pores are partly filled pores.

With regard to claims 5-8, 10, 18-19, 44 and 53, these claims are non-elected since Alt meets the Markush grouping of claim 1 by including a bioactive agent.

With regard to claims 11, 15, 45, 48 and 54, anti-thrombotic (col 5, line 33) is an anticoagulant.

With regard to claims 16-17, Alt's surface consists of bonded spheres which would present pores having interconnecting porosity and since the pores are interconnected, the pores therefore extend through the rigid material (not through the thickness of the rigid material).

With regard to claim 50, See column 3 lines 54-61

Claims 1-11, 14-15, 18-21 and 40-45 and 47-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Dayton (US 5578075). Dayton discloses an implantable prosthesis (title) comprising a rigid material (11, rigid since the stent must hold open the vessel) with pores (claim 1), wherein a filler comprising a bioactive agent (claim 1) thereof, is located within the pores, wherein said rigid porous material with the filler presents a smoother surface for fluid flow than pores without filler (this is inherent since a filled pore presents less surface roughness).

With regard to claims 3, 43 and 52, as presented in claim 1 the filler presents a smooth surfaces to flow as compared to unfilled.

With regard to claim 4, filled pores are partly filled pores.

With regard to claims 5-8, 10, 18-19, 44 and 53, these claims are non-elected since Dayton meets the Markush grouping of claim 1 by including a bioactive agent.

With regard to claims 11, 15, 45, 48 and 54, heparin (col 7, line 24) is an anticoagulant.

With regard to claims 14 and 47, Dayton discloses the use of antibodies (col 7, lines 24-30) which are disclosed in the present application as a progenitor attraction compound.

With regard to claims 20-21, Dayton specifies that the stent maybe made of polyurethane (col 6 last line).

With regard to claim 50, See column 8 lines 1-8

Claims 40-45 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Solovay (US 5,769,884). Solovay discloses an implantable medical device comprising a rigid material (30) having pores (abstract) and a filler (col 6) comprising hydrogel, a structural protein, a bioactive agent, or a mixture thereof (lines 47-55) to promote cellular attachment and proliferation.

With regards to claims 43 and 52, the filled pores inherently present a smooth surface to flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

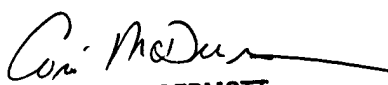
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-13, 46 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Steinke et al (US 6033436). Dayton discloses an implantable prosthesis as discussed above. However, Dayton does not specifically disclose the use VEGF. Steinke et al discloses another implantable prosthesis using VEGF (col 9 lines 57-58) as a bioactive agent to promote angiogenic response. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use VEGF as taught by Steinke et al in the implantable prosthesis as disclosed by Dayton in order to promote angiogenic response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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